UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:16CR00055 HEA/SPM
	)	
GEORGE PATINO,	)	
	)	
Defendant.	)	

INDICTMENT

The Defendant

The Grand Jury charges that:

1. At all times relevant to this Indictment, defendant George Patino, a/k/a Giorgio Paticciano Patino ("Patino"), was a resident of Houston, Texas. Patino operated an unlicensed wholesale drug distribution business from Texas and other locations. Patino conducted a number of drug transactions with persons located in St. Louis County, Missouri. Patino caused various packages of drugs to be mailed to addresses in St. Louis County, Missouri and transported drugs into interstate commerce into St. Louis County, Missouri. As such, Patino committed, continued, and completed offenses in this District.

Background

2. The U.S. Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDA's responsibilities included regulating the manufacture, labeling, and distribution of drugs shipped or received in interstate commerce.

3. Under the FDCA, "drugs" were defined as , among other things, "(A) articles recognized in the official United States Pharmacopoeia . . .; (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1).

4. Under the FDCA, "label" meant a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of [the FDCA] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper." 21 U.S.C. § 321(k). The FDCA defined "labeling" as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

5. Under the FDCA, a "new drug" was any drug which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 321(p)(1). In order to be lawfully marketed, sold or dispensed in the U.S., a new drug had to be the subject of an FDA-approved New Drug Application ("NDA"), Abbreviated New Drugs Application, or a notice of claimed exemption for an Investigational New Drug, pursuant to 21 U.S.C. § 355. The introduction into interstate commerce of an unapproved new drug was prohibited. 21 U.S.C. § 331(d).

6. A "prescription drug" under the FDCA was a drug that: (i) because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (ii) was limited by an application approved by FDA, to use under the professional supervision of a practitioner licensed by law to administer the drugs. 21 U.S.C. § 353(b)(1). HGH drug products are prescription drugs under 21 U.S.C. § 353(b)(1).

7. Prescription drugs were deemed to be misbranded if at any time, prior to dispensing, the label of the drug failed to bear, at a minimum, the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A). The "Rx only" symbol was used for prescription drugs, as opposed to over-the-counter drugs, which did not contain that symbol.

8. A drug was misbranded if its labeling failed to bear adequate directions for use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layman can use a drug safely and for the purposes for which it was intended. 21 C.F.R. § 201.5. By definition, prescription drugs could not have directions that allowed a layman to use them safely and for the purposes for which they were intended. 21 U.S.C. § 353(b); 21 C.F.R. § 201.5.

9. A drug was also misbranded if its labeling did not bear adequate warnings against use in those pathological conditions, and by children where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application, in such manner and form, as were necessary for the protection of users. 21 U.S.C. § 352(f)(2).

Human Growth Hormone

10. At times relevant and material herein: Human Growth Hormone (commonly known as HGH means Somatrem, Somatropin, or an analogue of either of these drugs. 21 U.S.C. § 333(e)(4). This drug is therapeutically equivalent to HGH created by the pituitary

gland of a healthy human being. HGH has been approved by the U.S. Food and Drug Administration ("FDA") for several narrow medical uses, such as short stature in children with chronic renal insufficiency disease or Turner or Prader-Willi syndromes or adults with wasting diseases associated with AIDS. The Food, Drug, and Cosmetic Act prohibits the knowing distribution of HGH for any use in humans other than for the treatment of disease or other recognized medical condition where such use has been authorized by the Secretary of the U.S. Department of Health and Human Services under 21 U.S.C. § 355 and pursuant to the order of a physician. 21 U.S.C. § 333(e). The FDA has not authorized HGH under 21 U.S.C. § 355 for any body-building, anti-aging, or weight loss treatment. Dispensing HGH in an attempt to improve a patient's athletic performance exposes the patient to numerous health risks, including liver and kidney tumors, liver and prostate cancer, heart attacks, and high blood pressure.

Defendant's Distribution of HGH

11. Defendant Patino operated a wholesale drug distribution business that sold unapproved HGH to assorted purchasers in the United States, including purchasers located in St. Louis County, Missouri. Patino's business typically sourced unapproved HGH from Mexico or China, and then smuggled the drugs into the United States via mailed packages containing individuals' drug orders.

12. On or about March 30, 2014, a Missouri doctor contacted an associate of Patino, seeking HGH for use at his clinic for male patients who wanted increased energy, strength, endurance, and athletic ability. Patino's associate advised the Missouri doctor that because of "heat" from "USA and FDA for processing growth hormone," credit cards could not be used for purchasing HGH. Instead, Patino's associate told the Missouri doctor to fund HGH transactions by sending direct deposits to Patino's bank account at a Houston, Texas bank.

13. From on or about March 30, 2014 through on or about July 1, 2015, Patino and the Missouri doctor engaged in numerous HGH transactions for approximately 40 local HGH patients, with the Missouri doctor repeatedly sending direct deposits to Patino's bank account to fund individual drug purchases for assorted clinic patients. After the HGH arrived in St. Louis County, Missouri, the HGH was distributed and dispensed to local patients who wanted to increase their energy, strength, endurance, and athletic ability.

COUNT ONE

The Conspiracy

14. The Grand Jury adopts paragraphs 1-13 as and for paragraph 14.

15. From on or about March 30, 2014 through on or about July 1, 2015, in St. Louis County, Missouri, in the Eastern Division of the Eastern District of Missouri, and elsewhere, defendant GEORGE PATINO, and others known and unknown to the Grand Jury, did knowingly and willfully agree and conspire with others to commit the following offense against the United States, specifically the knowing distribution of Human Growth Hormone for uses other than the treatment of a disease or other recognized medical condition that has been authorized by the Secretary of U.S. Department of Health and Human Services under 21 U.S.C. § 355 – specifically, for bodybuilding, anti-aging, weight loss and increased athletic performance -- in violation of 21 U.S.C. § 333(e)(1).

Purpose of the Conspiracy

16. Defendant Patino, and others known and unknown to the Grand Jury, conspired to sell HGH to be utilized for purposes other than those lawfully approved by the FDA. Defendant distributed HGH in order to generate profit.

Manner and Means of the Conspiracy

17. The manner and means employed by Defendant and others to effect the object of the conspiracy were as follows:

a. Defendant Patino obtained the HGH discussed above from Mexico, China, and other locations, and shipped it to the Eastern District of Missouri.

b. Defendant Patino received payments from persons in the Eastern District of Missouri after distributing HGH to various addresses located in the Eastern District of Missouri.

Overt Acts

18. In furtherance of the conspiracy, and to effectuate the purpose of the conspiracy, the defendants and others committed and caused to be committed the following overt acts, among others:

a. On or about May 28, 2014, Defendant Patino caused a shipment of HGH to be shipped from Mexico to Missouri in the name of patient #1, identified in this Indictment by his initials W.R.) in St. Louis County, Missouri.

b. On or about December 9, 2014, Defendant Patino caused a shipment of HGH to be shipped from Mexico to Missouri that was addressed for delivery to a medical clinic in the name of patient #2 (B.W.) in St. Louis County, Missouri.

c. On or about May 13, 2015, Defendant Patino received a wire transfer from a bank in St. Louis County, Missouri of $650 into his bank account in Texas for a six month supply of HGH for patient #4 (B.S.) that was shipped to a medical clinic in St. Louis County, Missouri.

All in violation of 18 U.S.C. §§ 371 and 2.

COUNT TWO

19. The Grand Jury adopts paragraphs 1-13 and as for paragraph 19.

20. On or about May 28, 2014, in the Eastern District of Missouri, and elsewhere, defendant GEORGE PATINO, did knowingly distribute and possess with the intent to distribute Human Growth Hormone for any use in humans other than for treatment of a disease or other recognized medical condition by sending a package containing HGH from Mexico to St. Louis County, Missouri for patient #1 (W.R.), where such use has not been authorized by the Secretary of the U.S. Department of Health and Human Services under 21 U.S.C. § 355 and pursuant to the order of a physician. All in violation of 21 U.S.C. § 333(e)(1) and 18 U.S.C. § 2.

COUNT THREE

21. The United States adopts paragraphs 1-13 and as for paragraph 21.

24. On or about December 23, 2015, in the Eastern District of Missouri, and elsewhere, defendant GEORGE PATINO, aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain merchandise, that is, a package containing HGH, contrary to law, in that the package contained approximately 6 boxes of HGH that were misbranded within the meaning of 21 U.S.C. §§ 352(f)(1)-(2), in violation of 21 U.S.C. Section 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

A TRUE BILL.

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FOREPERSON

RICHARD G. CALLAHAN
United States Attorney

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A.U.S.A. ANDREW J. LAY, #39937